# In the United States Court of Federal Claims

# **OFFICE OF SPECIAL MASTERS**

No. 20-404V UNPUBLISHED

SHIRLEY UNDERWOOD.

Petitioner,

٧.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

**Chief Special Master Corcoran** 

Filed: January 6, 2023

Special Processing Unit (SPU); Ruling on Entitlement; Findings of Fact; Onset; Influenza (Flu); Shoulder Injury Related to Vaccine Administration (SIRVA)

Leigh Finfer, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Claudia Barnes Gangi, U.S. Department of Justice, Washington, DC, for Respondent.

## RULING ON ENTITLMENT<sup>1</sup>

On April 8, 2020, Shirley Underwood filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*<sup>2</sup> (the "Vaccine Act"). Petitioner alleges a Table injury - that she suffered a shoulder injury related to vaccine administration ("SIRVA") after receiving an influenza ("flu") vaccine on September 14, 2017. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters ("SPU").

<sup>&</sup>lt;sup>1</sup> Because this unpublished opinion contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the opinion will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

<sup>&</sup>lt;sup>2</sup> National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

After a full review of the evidence, I find it more likely than not that Petitioner experienced the onset of her injury within 48 hours of her vaccination; and that she is otherwise entitled to compensation.

# I. Relevant Procedural History

After the case's initiation and SPU assignment, I encouraged the parties to settle, but by June 2021 they informed me Respondent intended to defend this claim and that Petitioner would proceed filing a Motion for a Ruling on the Record. ECF No. 21; ECF No. 24. I therefore set deadlines for the filing of briefs addressing Petitioner's to compensation. ECF No. 25.

On August 26, 2021, Petitioner filed a Motion for Ruling on Record. ECF No. 27. On November 2, 2021, Respondent filed his Rule 4(c) Report and Response to Petitioner's Motion, recommending that entitlement to compensation be denied under the terms of the Vaccine Act. ECF No. 29. Specifically, Respondent argued that the evidence preponderated against a finding that the onset of Petitioner's shoulder pain occurred within 48 hours of her vaccination as required to establish an on-Table SIRVA claim. *Id.* at 5-7. A Reply brief was not filed. This matter is ripe for my resolution.

# II. Authority

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id*.

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. See Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." Sanchez v. Sec'y of Health & Hum. Servs., No. 11–685V, 2013 WL 1880825, at \*3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing Blutstein v. Sec'y of Health & Hum. Servs., No. 90–2808V, 1998 WL 408611, at \*5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,<sup>3</sup> a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F. R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying QAI are as follows:

Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time-frame;

<sup>3</sup> In summary, a petitioner must establish that he received a vaccine covered by the Program, administered

either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of his injury for more than six months, died from his injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. Section 11(c)(1)(A)(B)(D)(E).

- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

#### III. Relevant Factual Evidence

I have reviewed the entire record as it stands, but limit my discussion below to the evidence most relevant to my determination of whether Petitioner experienced the first post-vaccination symptom or manifestation of onset (specifically pain) occurred within 48 hours as set forth in the Vaccine Injury Table and Qualifications and Aids to Interpretation ("QAI") for a Table SIRVA. 42 C.F.R. § 100.3(a)(XIV)(B) (seasonal influenza vaccines); 42 C.F.R. § 100.3(c)(10)(ii) (required onset for pain listed in the QAI).

### A. Medical Records and Email Evidence

- On September 14, 2017, Petitioner received a flu vaccine in her right shoulder from a Walmart Pharmacy. Ex. 1 at 6.
- On September 15, 2017 (one day after her vaccination), Petitioner sent an email message to her daughter, Robin Underwood Doty, stating (in the subject line) "got my flu shot yesterday arm a little sore." Ex. 10.4
- On September 28, 2017, Petitioner was seen at the office of her primary care provider, Stephen O. Woodruff, MD, for a urinary tract infection ("UTI"). Ex. 2 at 64. Petitioner was evaluated by Joy Escue, ARPN. Id. In addition to complaints of urinary frequency, Petitioner also reported swelling in her left foot and ankle that subsided with rest, but returned in the morning. Id. Finally, the record notes that "[t]wo weeks ago she received the flu shot and reports that she has been feeling tired and achy since that time. She reports that she has stayed in bed for the past 2 weeks most of the time." Id. Petitioner was assessed with urinary frequency, UTI symptoms, long-term use of anticoagulant, and type 2 diabetes mellitus with

<sup>4</sup> Petitioner's daughter explains in an email to counsel dated May 7, 2021, that there was no text in the body

of the September 2017 email from her mother, and that she and her mother communicate using just the subject line in an email "like text messaging." Ex. 10. Petitioner confirmed this practice in a sworn declaration dated August 23, 2021. Ex. 11. Petitioner also submitted other examples of email communications with her daughter where they sent messages by email using only the subject line and no

- peripheral neuropathy. *Id.* at 67. No complaints specific to Petitioner's right shoulder were documented.
- On November 19, 2017, Petitioner messaged Dr. Woodruff requesting a refill of a muscle relaxant she was given when she "had a kidney stone" noting "she had a really tight muscle in [her] back." Ex. 5 at 2.
- Petitioner engaged in email correspondence with her daughter between December 2 and 5, 2017. Ex. 7. The emails document that her daughter was concerned about her mother's "arm," suggested she be seen by urgent care, as well as ice her arm to bring down the inflammation. Ex. 7 at 1-2, 4, 6. Petitioner's daughter also speculated her arm "is a combo of the bed and computer," and suggested she needed "range of motion physical therapy." Id. at 6. Petitioner reported to her daughter that "where I got the shot still scabs up ever[y] week [or] so." Id.
- Petitioner was seen by Dr. Woodruff on January 15, 2018 and reported right shoulder pain, among other things. Ex. 2 at 68. Dr. Woodruff's assessment included "[b]ursitis in [r]ight shoulder[,] [s]evere[,] [b]ut does not want shot today." Id. at 71. The onset of Petitioner's right shoulder pain is not described, or otherwise documented, in the record.
- On February 28, 2018, Petitioner presented again to Dr. Woodruff "[w]ith frozen [r]ight shoulder [a]fter Flu shot." Ex. 2 at 73. It was noted that Petitioner had "significant pain" in the right shoulder and was having trouble sleeping. *Id.* Dr. Woodruff administered a steroid injection into Petitioner's right shoulder and prescribed her Percocet to treat her pain. *Id.* at 76. Petitioner was assessed with frozen right shoulder and acute right shoulder bursitis. *Id.*
- On March 17, 2018, Petitioner messaged Dr. Woodruff about her arm. Ex. 5 at 1.
  She reported that "[s]ince I got my flu shot in September (6 months ago) it's gotten
  worse. At first it was just painful at the top of my arm and now I have extreme pain
  at times in my elbow, my hand, and in various fingers." She further reports she
  could "only move [her] arm from the elbow down." Id.
- On April 18, 2018, Petitioner underwent an initial physical therapy evaluation. The
  evaluation indicates that Petitioner presented with "major [complaints of] R[ight]
  shoulder/arm pain that started in September after getting a shot in her R[ight] arm.
  P[atien]t states that her shoulder got sore after the shot and it has been hurting
  since then." Ex. 4 at 7.

#### **B.** Declarations

Petitioner filed both a sworn and notarized affidavit, as well as a sworn declaration, in support of her claim. Ex 8; Ex. 11.

Petitioner states that she experienced "very little pain with the vaccination," but "[I]ater that day, my right shoulder was sore" and she emailed her daughter the following day regarding her "flu shot and arm pain." Ex. 8 ¶ 3. Petitioner states that "[w]ithin two days, my arm hurt a lot and I couldn't use it." *Id.* Petitioner indicates that she took muscle relaxants left over from her from a prior kidney stone treatment which helped and that sent a message to her doctor requesting a refill when the prescription ran out. *Id.* ¶ 4. Petitioner states that she tried to self-treat her shoulder pain using the muscle relaxants, Tylenol, Bengay, and a heating pad. *Id.* Petitioner notes her pain became so bad she had to see a doctor, hire a housekeeper, and engaged in email correspondence with daughter regarding her "ongoing right arm/shoulder symptoms." *Id.* 

Petitioner states that she did report her right shoulder pain to Dr. Woodruff at her September 28, 2017 appointment and that she does not know why it is not documented in the medical record. *Id.*  $\P$  5. She further indicates that he offered her a cortisone shot at that appointment and she declined it. *Id.* She states she next reported her shoulder pain to Dr. Woodruff on January 15, 2018, as documented in the record, but states that she also told the doctor that she had not been able to use her arm since her flu vaccination. *Id.*  $\P$  6. Petitioner further asserts she reported her shoulder pain again at her January 17, 2018 appointment (for a mammogram) but that it is also not documented in the record. *Id.*  $\P$  7.

# IV. Findings of Fact

The only Table requirement for SIRVA that Respondent contests is whether Petitioner's first post-vaccination symptom or manifestation of onset (specifically pain) occurred within 48 hours as set forth in the Vaccine Injury Table and Qualifications and Aids to Interpretation ("QAI") for a Table SIRVA. 42 C.F.R. § 100.3(a)(XIV)(B) (seasonal influenza vaccines); 42 C.F.R. § 100.3(c)(10)(ii) (required onset for pain listed in the QAI); ECF No. 29 at 5-7. Based upon a review of the entire record, and for the reasons set forth below, I find that it more likely than not was.

In this case, the medical record pertaining to the visit most contemporaneous to Petitioner's vaccination – from a visit to her PCP's office only two weeks later – omits specific mention of shoulder pain (although it does document achiness following her vaccination). Ex. 2 at 64-67. Respondent argues that Petitioner's recollection in her affidavit that she did report shoulder pain to Dr. Woodruff at this time is erroneous, and

that Petitioner likely conflated the earlier appointment with her January 15, 2018 appointment with Dr. Woodruff, as Petitioner was not evaluated by Dr. Woodruff on September 28, 2017, but was seen instead by a nurse at his practice, Joy Escue. ECF No. 29 at 6. Additionally, Respondent points out that Petitioner's November 19, 2017 message to Dr. Woodruff, requesting a refill of a muscle relaxant and noting "she had a really tight muscle in [her] back," contains no mention of shoulder pain, despite Petitioner asserting in her affidavit she was taking the muscle relaxants to treat her shoulder. Ex. 5 at 2.

Respondent reasonably questions the accuracy of Petitioner's recollection in her affidavit, and I cannot conclude that Petitioner reported *pain* per se at the September 28<sup>th</sup> doctor's visit. However, that does not preclude a finding that Petitioner suffered the onset of shoulder pain within 48 hours of her vaccination, given the other evidence in the record. As a preliminary matter, the medical record *does* document that Petitioner reported feeling achy at the September 28<sup>th</sup> treatment encounter. It is reasonable to conclude that Petitioner either did not detail the nature of her achiness (failed to explicitly report shoulder pain), or it was not documented, given that at that time Petitioner was experiencing symptoms of a UTI – an acute medical condition – that would have been the primary focus of the visit.

I have previously observed, "the Vaccine Act clearly does *not* require that symptoms be recorded within a specific timeframe to be preponderantly established. Rather, it requires only that onset *occurs* in the relevant timeframe." *Niemi v. Sec'y of Health & Hum. Servs.*, No. 19-1535V, 2021 WL 4146940, at \*4 (Fed. Cl. Aug. 10, 2021) (citing Section 13) (emphasis in original). Neither does the Act require that the medical records document an exact date that the onset of a petitioner's shoulder pain began. A special master may thus find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2).

In this case, Petitioner's allegation that her shoulder pain occurred within 48 hours of her vaccination is supported by *some* contemporaneous treatment records close-intime to the vaccination – even if not with the specificity Respondent would prefer. And later records establish that Petitioner reported her shoulder pain to her PCP on January 15, 2018 (albeit four months after her vaccination). Ex. 2 at 68-73. Although that record omits any description for the onset of Petitioner's shoulder pain, later records link her shoulder pain to her September 14, 2017 vaccination. On February 28, 2018, Petitioner reporting shoulder pain again to her PCP, who specified she presented "[w]ith frozen Right shoulder [a]fter Flu shot." Ex. 2 at 73. On March 17, 2018, Petitioner emailed her

PCP complaining that her shoulder pain persisted and was spreading, noting that "[s]ince I got my flu shot in September (6 months ago) it's gotten worse." Ex. 5 at 1. Again, at her initial physical therapy evaluation, the medical record documents "shoulder/arm pain that started in September after getting a shot in her R[ight] arm." Ex. 4 at 7. "P[atien]t states that her shoulder got sore after [her] shot and it has been hurting since then." *Id.* 

In addition, the contemporaneous email correspondence between Petitioner and her daughter are consistent with her allegations about onset. Petitioner sent her daughter an email *the day following* her vaccination indicating that her arm was a little sore. Ex. 10. This statement is consistent with Petitioner's later message to Dr. Woodruff that her arm had been sore since her vaccination, but had gotten worse. Ex. 5 at 1. Additionally, Petitioner's email correspondence with her daughter in December 2017 demonstrates that Petitioner and her daughter had ongoing concerns in regard to her arm pain. Ex. 7.

Based on the record as a whole, I find that Petitioner has established the onset of her injury within 48 hours of her vaccination. Admittedly, this finding represents a close call. I also note that Petitioner's delay in seeking medical treatment specific to her shoulder pain demonstrates that she was able to tolerate the pain initially and is indicative of a less severe SIRVA – a factor I will consider in awarding damages for pain and suffering in this case.

# V. Other Table Requirements and Entitlement

Based on the above, and my review of the record as a whole, Petitioner has established all requirements for a Table SIRVA claim. 42 C.F.R. §§ 100.3(a)(XIV)(B), (c)(10). However, even if a petitioner has satisfied the requirements of a Table injury or established causation-in-fact, he or she must also provide preponderant evidence of the additional requirements of Section 11(c), *i.e.*, receipt of a covered vaccine, residual effects of injury lasting six months, etc. See generally § 11(c)(1)(A)(B)(D)(E). But those elements are established or undisputed in this claim. I therefore find that Petitioner is entitled to compensation in this case. Thus, Petitioner has satisfied all requirements for entitlement under the Vaccine Act.

# Conclusion

Based on the entire record, I find that Petitioner has provided preponderant evidence satisfying all requirements for a Table SIRVA. Petitioner is entitled to compensation. A Damages Order will issue.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran Chief Special Master